

RESPONSE TO OFFICE ACTION

ATTY DOCKET : RM.WSM
APPLICANT(S) : Badr, et al.
SERIAL NO. : 10/523,743
FILED : November 14, 2005
INT'L S.N. : PCT/US2003/024188

Examiner: Christian Yongkyun Chang

Art Unit: 3735
Conf. No.: 7945
INT'L FILED: 01 August 2003

Priority

With respect to priority, Applicants gratefully acknowledge that the Examiner has acknowledged Applicant's claim of benefit of the filing date of Provisional Application 60/400,038 filed on 08/02/2002.

Information Disclosure Statement

With respect to an Information Disclosure Statement, the Examiner states that the listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. More specifically, the Examiner states that 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). In this regard, the Examiner directs Applicants' attention to MPEP § 609.05(a).

APPLICANTS' RESPONSE

Applicants have included herewith an Information Disclosure Statement in accordance with the Examiner's requirement. Accordingly, it is requested that the references cited in the Search Report be considered by the Examiner.

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Claim Objection

Claim 4 is deemed by the Examiner to be objectionable to under 37 CFR 1.75(c), as being of improper dependent form for failing to limit further the subject matter of a previous claim. The Examiner states that Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 4 is indicated by the Examiner to depend from claim 3, which claims a three-term polynomial function. The computation of the derivative of a three-term polynomial function, according to the Examiner, is inherently equivalent to the equation stated in claim 4, which, as the calculation of the derivative is claimed within independent claim 1, would, also according to the Examiner, be inherent within the language and scope of claim 3. Thus, the Examiner concludes that claim 4 fails to limit further the subject matter of a previous claim.

APPLICANTS' RESPONSE

Applicants have amended dependent claim 4 to depend from independent claim 1, instead of dependent claim 3. Since independent claim 1 does not specify the three-term polynomial function, the particular form of the derivative specified in amended dependent claim 4 is not inherent within the language and scope of independent claim 1 and serves to limit further the subject matter of dependent claim 1.

In view of the foregoing, it is respectfully asserted that the Examiner's objection to dependent claim 4 has been overcome.

Claims Rejections***Claims Rejections - 35 U.S.C. § 112, Second Paragraph***

Claims 5 and 6 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to point out with particularity and claim distinctly the subject matter that Applicants regard as the invention.

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As to claims 5, the Examiner states that the claim language states a "step of determining that a breath is inspiratory," with the result being considered "IFL" in the event that the derivative is greater or equal to zero. The specification shows that IFL stands for "Inspiratory Flow Limitation". It is unclear whether the step is determining that a breath is inspiratory or that an inspired breath is limited.

As to claim 6, the Examiner states that the claim language states a "step of determining a breath is inspiratory," with the result being considered "NIFL" in the event that the derivative is less than zero. The specification shows that "NIFL" stands for "Non-Flow Limited". It is unclear whether the step is determining that a breath is inspiratory or that an inspired breath is non-limited.

APPLICANTS' RESPONSE

Applicants have amended the claims that the Examiner has rejected under 35 U.S.C. § 112, second paragraph, to specify the invention with greater particularity. More specifically, dependent claim 5 has been amended to specify that the IFL result corresponds to snoring. Conversely, dependent claim 6 has been amended to specify that the NIFL result corresponds to a breath without snoring. This definition is derived from the specification (see, WO2004/012597 A1) at page 4, beginning of the first full paragraph, wherein it is stated that:

"[i]nspiratory flow limitation ("IFL") is the mechanical corollary of snoring and corresponds to a narrowing of the upper airway of a patient. The detection of inspiratory flow limitation will improve the diagnosis of sleep disordered breathing.

In view of the foregoing, it is respectfully asserted that the Examiner's rejections of claims 5 and 6 under 35 U.S.C. § 112, second paragraph, have been overcome.

Claims Rejections - 35 U.S.C. § 103**CLAIMS 1-4, 8-10, 15-17, AND 22**

Claims 1-4, 8-10, 15-17, and 22 stand rejected under 35 U.S.C. § 103(a) as specifying subject matter considered by the Examiner to be obvious over the Tham, et al. reference

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(United States Patent No.6,068,602) in view of the Starr, *et al.* reference (United States Patent No.6,342,040).

As to claim 1, the Examiner states that the Tham, *et al.* reference teaches a method of measuring upper airway resistance of a human patient (Abs), the method, according to the Examiner, comprising the steps of:

obtaining air pressure data from an air pressure data signal corresponding to a plurality of breathing cycles while the human patient is asleep (Abs; col. 2, lines 9-19);
(The Examiner concedes that although the Tham, *et al.* reference does not explicitly teach that the human patient is asleep, the reference is considered by the Examiner to teach that the device is particularly useful in anesthesia applications. It is the Examiner's position that a patient induced into anesthesia is in a state of sleeping);
obtaining air flow data from an air flow data signal corresponding to the plurality of breathing cycles while the human patient is asleep (Abs; col. 2, lines 9-19);
transferring the air pressure data and the air flow data to a processor (col. 3, lines 14-36);
storing the air pressure data and the air flow data in respective correlated storage regions of a matrix program system of the processor (col. 5, line 51-61);
segregating the air pressure data and the air flow data in the matrix program of the processor into corresponding breathing cycles of the human patient (col. 5, line 51-61);
computing normalized air pressure data to achieve a predetermined normalized air pressure value to correspond with a predetermined point for each breathing cycle of the human patient (Abs; col. 2, lines 20-34; col. 2, lines 50-60);

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producing a correlation of the air flow data against normalized air pressure data (col. 3, lines 52-64);

curve-fitting onto the correlation of the air flow data against normalized air pressure data a curve corresponding to a predetermined multiple term mathematical function (col. 4, lines 42-49);

computing the value of the coefficients of the predetermined multiple term mathematical function (col. 5, lines 17-50).

According to the Examiner, the Tham, *et al.* reference fails to teach the computing of the derivative of the predetermined multiple term mathematical function. However, the Starr, *et al.* reference is considered by the Examiner to teach a diagnostics device for monitoring a snoring patient during sleep (col. 3, lines 42-52), wherein a third order equation is used to fit the curves for a voltage-flow relationship (col. 11, lines 48-66), and a derivative calculated to determine a quantitative snore flow signal (col. 16, lines 36-56), which can be utilized to determine sleep apnea. In addition, the Examiner continues by stating that the calculation of a derivative is well known in the art to determine properties of a mathematical function such as the rate of change. Hence, the Examiner concludes that it would have been obvious to one of ordinary skill in the art to modify the Tham, *et al.* reference with the Starr, *et al.* reference to determine further properties of a determined function.

As to claim 2, the Examiner states that the Tham, *et al.* reference teaches a method wherein in said step of curve-fitting onto the correlation of the air flow data against normalized air pressure data a curve, the predetermined multiple term mathematical function is a quadratic function, $F(P)=AP^2+BP+C$, where A, B, and C are coefficients (col. 4, lines 39-49).

As to claim 3, the Examiner states that the Tham, *et al.* reference teaches a method wherein in said step of curve-fitting onto the correlation of the air flow data against normalized air pressure data a curve, the predetermined multiple term mathematical function is a three

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term polynomial function $F(P)=AP^3+BP^2+CP+D$, where A, B, C, and D are coefficients (col. 4, lines 39- 49).

As to claim 4, the Examiner concedes that the Tham, *et al.* reference fails to teach a step of computing the derivative. However, the Examiner nevertheless asserts that it would have been obvious to do so, for the reasons that the Examiner has previously indicated.

As to claim 8, the Examiner states that the Tham, *et al.* reference teaches a method of determining a flow-limiting characteristic of the upper airway of a human patient, the method comprising the steps of (Abs):

obtaining air pressure data from an air pressure data signal corresponding to a plurality of breathing cycles while the human patient is asleep (Abs; col. 2, lines 9-19);
obtaining air flow data from an air flow data signal corresponding to the plurality of breathing cycles while the human patient is asleep (Abs; col. 2, lines 9-19);
transferring the air pressure data and the air flow data to a processor (col. 5, lines 51-61);
storing the air pressure data and the air flow data in respective correlated storage regions of a matrix program system of the processor (col. 5, line 51-61);
segregating the air pressure data and the air flow data in the matrix program of the processor into corresponding breathing cycles of the human patient (col. 5, line 51- 61);
computing normalized air pressure data to achieve a predetermined normalized air pressure value to correspond with a predetermined point for each breathing cycle of the human patient (col. 2, lines 43-60; col. 4, lines 58-67); and
computing the flow-limiting characteristic of the upper airway of a human patient as a function of normalized air pressure data divided by corresponding air flow data (col. 4, lines 58-67).

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As to claim 9, the Examiner states that the Tham, *et al.* reference teaches a method wherein the matrix program system is a spreadsheet program system, the air pressure data and the air flow data being arranged in respective spreadsheet columns correlated by rows (col. 5, line 51-61).

As to claim 10, the Examiner states that the Tham, *et al.* reference teaches a method wherein said step of computing normalized air pressure data comprises the further step of storing the normalized air pressure data in a respective spreadsheet column correlated by rows into corresponding breathing cycles of the human patient (col. 5, line 51-61).

As to claim 15, the Examiner states that the Tham, *et al.* reference teaches a method wherein the air pressure data and the air flow data are sampled a plurality of times during each breathing cycle (col. 2, lines 43-60).

As to claim 16, the Examiner states that the Tham, *et al.* reference teaches a method wherein said step of computing the flow-limiting characteristic of the upper airway of a human patient is performed a corresponding plurality of times during each breathing cycle (col. 2, lines 43-60).

As to claim 17, the Examiner states that the Tham, *et al.* reference teaches a method wherein said step of computing the flow-limiting characteristic of the upper airway of a human patient is performed a corresponding plurality of times during each breathing cycle and during which the air flow data has a predetermined value (col. 5 line 62 to col. 6, line 8).

As to claim 22, the Examiner concedes that the Tham, *et al.* reference fails to teach the method wherein there is provided the further step of producing a data array corresponding to the flow-limiting characteristic wherein the normalized air pressure data corresponds to the x-axis and the air flow data corresponds to the y-axis. However, the Examiner asserts that the plotting of data to a graph is well known in the art and would have been obvious for one or ordinary skill in the art to modify the teaching in the Tham, *et al.* reference with a graph plotting step to allow easier visualization of data.

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APPLICANTS' RESPONSE

With respect to independent claim 1, Applicants have amended this claim to include therein the subject matters of dependent claims 2 and 7. Dependent claim 7 (now canceled) had been determined by the Examiner to be merely objectionable as depending from a rejected base claim. Accordingly, it is respectfully asserted that the Examiner's rejection of independent claim 1 under 35 U.S.C. § 103(a) has been overcome. Claims 3 and 4, which are also subject to the Examiner's rejection under 35 U.S.C. § 103(a), all depend from amended independent claim 1, and therefore all contain the same limitations as the amended independent claim. Accordingly, these claims are also believed to be in allowable condition. The Examiner's rejection of dependent claim 2 has been rendered moot by operation of the cancellation thereof.

With respect to independent claim 8, Applicants have amended this claim to include therein the subject matter of dependent claim 11, which the Examiner has deemed to be merely objectionable as depending from a rejected base claim. Accordingly, it is respectfully asserted that the Examiner's rejection of independent claim 8 under 35 U.S.C. § 103(a) has been overcome. Claims 8-10, 15-17, and 22, which are also subject to the Examiner's rejection under 35 U.S.C. § 103(a), all depend from amended independent claim 8, and therefore all contain the same limitations as the amended independent claim. Accordingly, these claims are also believed to be in allowable condition.

In view of the foregoing, it is respectfully asserted that the Examiner's rejection of claims 1-4, 8-10, 15-17, and 22 under 35 U.S.C. § 103(a) has been overcome, and that all claims that remain in the present case are in allowable condition.

The Examiner's Indication of Allowable Subject Matter

Applicants gratefully acknowledge that the Examiner has determined that claims 23-34 are allowed.

Applicants further gratefully acknowledge that the Examiner has determined that claims 5 and 6 are merely objectionable and would be allowable if rewritten or amended to overcome

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the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in the Examiner's action, as well as rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants further gratefully acknowledge that the Examiner has determined that claims 5-7, 11-14, and 18-21 are merely objectionable to as depending from a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The Examiner's Statement of Reasons for Allowability of Claims

The following is a statement of reasons issued by the Examiner for the indication of allowable subject matter:

As to claims 5 and 6, the Examiner states that the prior art of record fails to teach a step wherein the derivative is used to determine whether breath is non-flow limited or flow limited.

As to claims 7 and 23, the Examiner states that the prior art of record fails to teach a step of computing a resistance corresponding to the reciprocal of coefficient C.

As to claim 11, the Examiner states that the prior art of record fails to teach that each breathing cycle of the human patient is determined in relation to the predetermined point thereof corresponding to the predetermined normalized air pressure value.

The Examiner states that claims 12-14 are indicated as allowable subject matter in that they depend from claim 11.

As to claim 18, the Examiner states that the prior art of record fails to teach a step of correlating air flow data and normalized pressure data to form a data correlation in an array, and the predetermined within a substantially linear portion of the data correlation.

The Examiner states that claims 19-21 are indicated as allowable subject matter in that they depend upon claim 18.

Claims 24-34 are indicated by the Examiner to be allowable in that they depend from claim 23.

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Conclusion

In view of the foregoing, it is respectfully requested that the Examiner reconsider the present application, allow the claims, and pass the application for issue. If the Examiner believes that the prosecution of this case can be expedited by a telephone interview, the Examiner is requested to call attorney for Applicants at the telephone number indicated hereinbelow.

Respectfully submitted,



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RAM:rb:ROA-091208.WSM

enc Annexure 1 (Amended Claims)
Information Disclosure Statement
File: ROA-091208.WSM